UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,208	11/16/2005	Walter Gumbrecht	0250109	5284

30596 7590 01/04/2008

HARNESS, DICKEY & PIERCE, P.L.C.
P.O.BOX 8910
RESTON, VA 20195

EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	**PAPER NUMBER**
1634	
MAIL DATE	**DELIVERY MODE**
01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,208	GUMBRECHT ET AL.	
	Examiner	Art Unit	
	Narayan K. Bhat	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 20 June 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6/20/2005 and 3/16/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Application is the National Stage of International Application filed on November 16, 2005.

2. Claims 1-20 are pending in this application and are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 9 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Albers et al (WO 00/62048, published Oct. 19, 2000), which was not published in English. The US equivalent USPN 7,208,077 is deemed an English translation. The content of the WO 00/62048 are deemed to be identical to the USPN 7,208,077, because of the 371 status of the '077 patent.

Regarding claim 1, Albers et al teaches a DNA chip comprising planar substrate, i.e., a flat carrier (Fig. 1a, # 1, column 5, lines 37-38) and further teaches multiple electrodes, each being arranged in an array position (Fig. 1b, electrodes -# 3a and 3a', array position # 4, column 9, lines 18-22), thus teaching an array of spots. Albers et al also teaches that each electrode has a sensor position to which catcher molecules are

linked (Fig. 1b, electrode # 3a, sensor position # 4, columns 9 and 12, lines 18-22 and 64-65) for the detection of binding events between catcher molecules and target molecules (Examples 8 and 10). It is noted that the binding events are intended use of the capture molecules. Teachings of Albers et al, thus encompass an array of spots containing catcher molecules, each spot being assigned a microelectrode arrangement for its intended use for detecting binding events between the catcher molecules and target molecules applied by means of via an analyte solution.

Albers et al also teaches that the sensor molecules on the electrodes (Albers et al also refers catcher molecules as sensor molecules) are covered with hydrogels (column 16, lines 18), which are hydrophilic as defined by and a preferred hydrophilic reaction layer recited in claim 6 of the instant invention.

Albers et al also teaches that hydrogel is permeable to target analyte and the analytes bind to the catcher molecules by diffusion process (column 23, lines 25-35), thus teaching the electrode arrangement being partially embedded in a hydrophilic reaction layer which is permeable to target molecules and in which immobilized catcher molecules are distributed three- dimensionally.

Regarding claim 9, Albers et al teaches that the reaction layer is hydrogel (column 16, lines 14-18).

Regarding claim 11, Albers et al teaches that the electrode arrangement is an interdigital electrode arrangement (Fig. 1, column 7, lines 39-41).

Regarding claim 12, Albers et al teaches an interdigital electrode arrangement comprising annular ultra microelectrode (Fig. 2b, electrode # 3a) and auxiliary electrode

(Fig. 2a, auxiliary electrode – # 3b, column 8, lines 35-65) and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a two-pole microelectrode system.

Regarding claim 13, Albers et al teaches an interdigital electrode arrangement comprising ultra microelectrodes (Fig. 2c, electrodes # 3, 3') and pair of auxiliary electrodes (Fig. 2a, auxiliary electrodes – # 3b, 3c, column 8, lines 35-65), and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a four-pole microelectrode system.

Regarding claim 14, Albers et al teaches a DNA chip that includes a planar substrate, i.e., flat carrier (Fig. 1a, # 1, column 5, line 37), which includes a silicon substrate, i.e., semiconductor layer (Fig. 1d, # 1s, column 9, lines30-31) and an insulating layer connected thereto (Fig. 1d, # 2, column 9, line 30), the insulating layer latter carrying the electrode arrangement (Fig. 1d, electrodes # 3a and 3a') and further teaches that the capture molecules are linked to the electrode surface and is covered by hydrogel, i.e., a reaction layer (column 16, lines 14-18), which is on its side remote from the semiconductor layer (Fig. 1d, sensor location area # 4, semiconductor layer # 1s).

Regarding claim 15, Albers et al teaches in that the semiconductor layer is a silicon layer (Fig. 1d, # 1s, column 9, lines 30-31).

5. Claims 1-2, 8-9 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Cote et al (USPN 6,485,703 issued Nov. 26, 2002).

Regarding claim 1, Cote et al teaches a flat carrier (Fig. 17 C, bottom layer, column 16, lines 56-58) and further teaches multiple hydrogel coated electrodes (Fig. 17 D, electrodes # 10, column 16, lines 59-61). Each hydrogel coated electrode of Cote et al is the array of spots of the instant claim. Cote et al also teaches analyte sensitive material, i.e., catcher molecules are attached to the hydrogel (column 7, lines 48-52) for its intended use for detecting binding events between the catcher molecules and target molecules applied by means of via an analyte solution (column 7, lines 52-56). Since electrodes are coated with hydrogel, they are partially embedded in a hydrogel. Cote et al also teaches that the hydrogel is hydrophilic (column 7, lines 33-38). Cote et al also teaches an arrangement of electrodes (Fig. 17 D, multiple hydrogel coated electrode- # 10, counter electrode - # 20, reference electrode- # 30) and further teaches that the electrodes detect a current upon detection of analyte by the hydrogel containing catcher molecules (column 16, lines 61-63), thus teaching the electrode arrangement being partially embedded in a hydrophilic reaction layer which is permeable to target molecules and in which immobilized catcher molecules are distributed three-dimensionally (column 34, lines 30-33).

Regarding claim 2, Cote et al teaches that the thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (column 41, line 54-55).

Regarding claims 8 and 18, Cote et al teaches that the hydrogel, i.e., a reaction layer contains coupling groups for the covalent binding of catcher molecules (column 7, lines 9-14).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-6, 8, 15-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al (WO 00/62048, published Oct. 19, 2000) in view of Cote et al (USPN 6,485,703 issued Nov. 26, 2002) and further in view of Zhou et al (USPGPUB NO. 2004/0121339 filed Dec. 19, 2002).

Teachings of Albers et al regarding claim 1 are described previously in this office action.

Regarding claim 2, Albers et al teaches that the sensor molecules on the electrodes (Albers et al also refers catcher molecules as sensor molecules) are covered with hydrogels (column 16, lines 18).

Regarding claims 3 and 4, Albers et al teaches that the electrode has a width of 1 micrometer and the spacing of 0.9 micrometer (column 26, lines 35-37).

Regarding claim 5, Albers et al teaches an interdigital electrode arrangement comprising annular ultra microelectrode (Fig. 2b, electrode # 3a) and auxiliary electrode (Fig. 2a, auxiliary electrode – # 3b, column 8, lines 35-65) and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a two-pole microelectrode system.

Regarding claim 6, Albers et al teaches an interdigital electrode arrangement comprising ultra microelectrodes (Fig. 2c, electrodes # 3, 3') and pair of auxiliary electrodes (Fig. 2a, auxiliary electrodes – # 3b, 3c, column 8, lines 35-65), and potentiostat (Fig. 6, # 34) and microcontroller/PC (Fig. 6), thus teaching the interdigital electrode arrangement and system, which can be configured to a four-pole microelectrode system.

Regarding claim 16, Albers et al teaches that the electrode has a spacing of 0.9 micrometer (column 26, lines 35-37).

Regarding claim 19, Albers et al teaches that the reaction layer is hydrogel (column 16, lines 14-18).

Regarding claim 20, Albers et al teaches that the electrode arrangement is an interdigital electrode arrangement (Fig. 1, column 7, lines 39-41).

Regarding claims 2-6 and 16, Albers et al teaches hydrogel layer but silent about the size of the reaction layer thickness. However, the size of the reaction layer thickness

was known in the art at the time of the claimed invention was made as taught by Cote et al, who teaches thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (Cote et al, column 41, line 54-55, limitation of claim 2).

Albers et al in view of Cote et al do not teach the reaction layer thickness of between 2 and 10 micrometer (limitation of claims 3 and 16) or thickness of approximately 3 micrometer (limitation of claim 5) or thickness of approximately 7 micrometer (limitation of claim 6). However, range of thickness of the reaction layer to attach catcher molecules was known at the time of the claimed invention was made as taught by Zhou et al, who teaches bio-microarrays and teaches the polyelectrolyte film, i.e., reaction layer and further teaches the thickness of the polyelectrolyte film ranges from 1 nanometer to 100 micrometers or from 5 nanometers to 20 micrometers or from 50 nanometers to 1micrometer (paragraph 0030), thus providing the thickness recited in said claims. Zho et al also teaches that the polyelectrolyte film are formed without any synthesis work or special equipment and provide a biologically friendly, solution like environment for biological immobilization of probes and is more sensitive for detecting analytes (Fig. 3, paragraph 0031).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include polyelectrolyte film of varying thickness of Zhou et al in the DNA chip of Albers et al in view of Cote et al with the expected benefit of having a polyelectrolyte film not needing synthesis work or special equipment and providing a biologically friendly, solution like environment for biological immobilization of probes and

is more sensitive for detecting analytes as taught by Zhou et al (Fig. 3, paragraph 0031).

Regarding claims 8 and 18, Albers et al teaches hydrogel layer but silent about the hydrogel layer containing coupling groups for the covalent binding of catcher molecules. However, the hydrogel layer containing coupling groups for the covalent binding of catcher molecules was known at the time of the claimed invention was made as taught by Cote et al, who teaches that the hydrogel, i.e., a reaction layer contains coupling groups for the covalent binding of catcher molecules (column 7, lines 9-14) and further teaches proper choice of hydrogel enhance the speed and sensitivity of analyte detection (column 10, lines 29-38). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the selected hydrogel of Cote et al in the DNA chip of Albers et al with the expected benefit of enhancing the speed and sensitivity of analyte detection as taught by cote et al (column 10, lines 29-38).

9. Claims 1-3, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albers et al (WO 00/62048, published Oct. 19, 2000) in view of Cote et al (USPN 6,485,703 issued Nov. 26, 2002) as applied to claim 1 above and further in view of Valint et al (USPG PUB NO. 2002/0102415 published Aug. 1, 2002).

Claim 10 is dependent from claim 6, which is dependent from claim 3, which is dependent from claim 2, which is dependent from claim 1. Teachings of Albers et al in view of Cote et al regarding claims 1-3 and 6 are described previously in this office action.

Regarding claim 10, Albers et al in view of Cote et al teaches a hydrogel (Albers et al, column 16, lines 14-18), and fCote et al teaches hydrogel polymers include PEG monomers (Cote et al, column 18, lines 17-67) or vinyl containing monomers (Cote et al, column 19, lines 29-67) or copolymers containing vinyl and methylacrylamate monomers (column 7, lines 9-12) but silent about hydrogel is an acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups. However, acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups was known at the time of the claimed invention was made as taught by Valint et al who teaches that the hydrogel comprise an acrylamide-based radical cross linkable hydrogel, which includes one maleic anhydride and glycidyl methacrylate as coupling groups (paragraph 0071).

Valint teaches that hydrogel with copolymers, e.g., maleic anhydride and glycidyl methacrylate is advantageous in providing a thicker coating by promoting the aggregation of the hydrophilic polymer, i.e., hydrogel in solution (paragraph 0067). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the hydrogel with copolymers of Valint et al in the DNA chip of Albers et al in view of cote et al with the expected benefit of providing a thicker coating by promoting the aggregation of of the hydrophilic polymer, i.e., hydrogel in solution as taught by Valint et al (paragraph 0067).

10. Claims 1-2, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al (USPN 6,485,703 issued Nov. 26, 2002) in view of Valint et al (USPG PUB NO. 2002/0102415 published Aug. 1, 2002).

Claim 17 is dependent from claim 2, which is dependent from claim 1. Claim 7 is dependent from claim 1. Teachings of Cote et al regarding claims 1 and 2 are described previously in this office action.

Regarding claims 7 and 17, Cote et al teaches that the thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (column 41, line 54-55) but silent about its thermal stability. However, thermal stability of hydrogel was known at the time of the claimed invention was made as taught by Valint et al who teaches a hydrogel polymer that is resistant to heat up to 90C, i.e., approximately 95C (paragraph 0217). Valint et al further teaches that hydrogel having thermal stability is sterilized easily using conventional autoclave without changes in its property (paragraph 0152, Table 13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the thermally stable hydrogel of Valint et al in the analyte sensor chip of Cote et al with the expected benefit of sterilizing hydrogel using conventional autoclave, still retaining its property as taught by Valint et al (paragraph 0152), thus having hydrogel without any microbial contamination in the analyte sensor chip of Cote et al.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-6, 8-9, 11-16 and 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/539,817 in view of Cote et al (USPN 6,485,703 issued Nov. 26, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claims 1, 8 and 17 of the '817 copending application are drawn to a DNA chip comprising a carrier, a microarray of spots arranged on the carrier, containing immobilized catcher molecules, each spot containing a thin-film four –pole system configured to measuring binding events between the catcher molecule and target analytes. Claims 8 and 17of the '817 copending application are further drawn to thin-film microelectrode system embedded in a reaction layer and the reaction layer is hydrogel.

Claims of '817 are not drawn to thickness of the reaction layer. However, Cote et al, teaches the reaction layer thickness of the hydrogel film, i.e., reaction layer is 100 micrometer (column 41, line 54-55) and further teaches proper choice of hydrogel enhances the speed and sensitivity of analyte detection (column 10, lines 29-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the selected hydrogel of Cote et al with the expected benefit of enhancing the speed and sensitivity of analyte detection as taught by cote et al (column 10, lines 29-38). Hence, claims 1-6, 8-9, 11-16 and 18-20 of the instant application are obvious over claims 1-18 of the '817 copending application in view of Cote et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat, Ph. D.

Examiner

Art Unit 1634